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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/708,815

03/26/2004

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27128 7590 01/23/2007  
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EXAMINER

SMITH, CAROLYN L

ART UNIT

PAPER NUMBER

1631

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|-----------|---------------|
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3 MONTHS

01/23/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/708,815 | <b>Applicant(s)</b><br>FISCHER ET AL. |  |
|                              | <b>Examiner</b><br>Carolyn L. Smith  | <b>Art Unit</b><br>1631               |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 November 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-43 is/are pending in the application.  
     4a) Of the above claim(s) 18-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☒ Claim(s) 6,7 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Applicants' elections with traverse of Group I (claims 1-17), filed 11/21/06, are acknowledged. Claims 18-43 are withdrawn from consideration as being drawn to non-elected Groups.

Applicants' traversal is on the grounds that Groups I-III are related, have a common utility of managing chemical compound development processes, and do not pose a serious burden for the examiner by requiring separate searches.

The applicants' request to combine Groups I-III into one invention was found unpersuasive because of the following reasons (summarized from the restriction paper):

Inventions I and [II and III] are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the inventions of Groupings I and [II and III] are distinct inventions because the method of Group I could be done manually.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions in Groups II and III are directed to different entity types that are not required one for the other and/or achieve different goals. For Group II, is directed to molecule and synthesis databases for

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synthesis of a particular target molecule without referencing which differs from Group III.

Group III is directed to a computer readable medium comprising a project header data structure with a project identifier and a data structure containing synthesis plans with molecular identifiers for referencing which is not found in the other Groups.

The requirements are still deemed proper and are therefore made FINAL.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title is directed to a method and structure for automated active pharmaceutical development, whereas in contrast the elected claims are specifically directed to a method for chemical compound development project management.

Claims herein under examination are 1-17.

### ***Claim Objections***

Claims 6 and 7 are objected to because of the following minor informalities: Claim 6 recites the word "GANTT" in capital letters. It does not appear that this word is an acronym, so the letters "ANTT" should not be capitalized. Claim 7 recites the number "5" in line 6 which is grammatically improper. Appropriate correction is requested.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Under the Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility (published in the O.G. notice (1300 OG 142) on 11/22/2005) a method that does not result in a physical transformation of matter MAY be statutory where it recites a concrete, tangible and useful result; i.e. a practical application.

In the instant case, the claims are directed to a method for chemical compound development project management. Claims 1-14 do not appear to result in a physical transformation of matter or recite a concrete, TANGIBLE, and useful result. Therefore, claims 1-14 are considered to be non-statutory subject matter.

While some claims recite “generating” limitations, these limitations may be interpreted to take place solely within a computer such that they are not necessarily displayed or otherwise communicated to a customer (user). For example, a “bill” as recited in instant claim 3 is simply a list of data that may be a concrete result. But unless the “bill” is displayed to the user, then what is generated is just a data listing held in computer memory that is not a TANGIBLE result. In reference to generating an estimated project cost (i.e. instant claim 7), computers generate cost estimates all the time, but not necessarily output them. It is noted that amending in a limitation

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of displaying the result to a user (provided there is written support in the originally filed application) would nullify this rejection.

It is noted that instant claims 15 and 16 together indicate that something is being communicated to the customer, so claims 15 and 16 as well as dependent claim 17 are statutory subject matter.

***Claims Rejected Under 35 U.S.C. § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

The preamble of claim 1 recites “a method for chemical compound development project management” whereas the body of the claim does not recite any type of management. Therefore, it is unclear if the preamble or the body of the claim is controlling the metes and bounds of claim 1. Clarification of this issue via clearer claim wording is requested. Claims 2-8 are also rejected due to their dependency from claim 1.

Claim 8 recites the term “using” which is vague and indefinite. It is unclear whether this “using” term is intended to be an actual step or merely some limitation of the data applied to the searching. If “using” is intended to be a step, it is unclear what step or steps are intended to be

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performed to carry out the “using” limitation. Clarification of this issue via clearer claim wording is requested.

Claim 9 recites the term “using” (lines 11 and 12) which is vague and indefinite. It is unclear whether this “using” term is intended to be an actual step or merely some limitation of the data applied to the generating. If “using” is intended to be a step, it is unclear what step or steps are intended to be performed to carry out the “using” limitation. Clarification of this issue via clearer claim wording is requested. Claims 10-17 are also rejected due to their dependency from claim 9.

Claims 10 (line 3), 11-14 (last lines), 16 (lines 2-3 and 5) and 17 (lines 2-3) recite the limitation "the target molecule". There is insufficient antecedent basis for this limitation in these claims as claim 9 (from which claims 10, 11, 16, and 17 depend) recites two target molecules (claim 9, lines 6 and 11) that are not necessarily the same target molecule. Therefore, it is unclear which particular target molecule is being referred to in claims 10 (line 3), 11-14 (last lines), 16 (lines 2-3 and 5) and 17 (lines 2-3). Clarification of this issue via clearer claim wording is requested.

Claim 15 recites the limitations "the target molecules" (line 2) and “the target molecule” (line 4). There is insufficient antecedent basis for these limitations in these claims as claim 9 (from which claim 15 depends) recites two target molecules (claim 9, lines 6 and 11) that are not necessarily the same target molecule. Therefore, it is unclear which particular target molecule is being referred to in claims 15 (line 4) and if two of one type or one of each of the previously mentioned target molecules is being referred to in claim 15 (line 2). Clarification of this issue



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via clearer claim wording is requested. Claims 16-17 are also rejected due to their dependency from claim 15.

Claim 15 recites the limitation "the estimated total cost" in the last line. There is insufficient antecedent basis for this limitation in the claim as there is only previous mention of plural costs. Therefore, it is unclear which particular total costs are being referred to in the singular "total cost" in line 6. Clarification of this issue via clearer claim wording is requested. Claims 16-17 are also rejected due to their dependency from claim 15.

Claim 16 recites the limitation "the synthesis plans" in line 4. There is insufficient antecedent basis for this limitation in the claim as there is only previous mention of a singular plan. Therefore, it is unclear which plural plans are being referred to in line 4. Clarification of this issue via clearer claim wording is requested. Claim 17 is also rejected due to its dependency from claim 16.

### ***Claim Rejections – 35 USC §102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5 and 7-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Mydlowec et al. (US 6,571,226 B1).



Mydlowec et al. disclose a method for chemical compound development project management (title and abstract) by providing a molecule database with molecular information including reagents to produce a target molecule (col. 2, lines 60-63; col.3, lines 43-47; and col. 5, lines 1-24), providing a synthesis database including activity information (col. 5, lines 25-35), and deriving information from the databases regarding the synthesis project (col. 5, paragraphs 5 and 6) including generating a synthesis plan for a target molecule (col. 2, paragraph 7) via querying the chemical and reaction databases (col. 8, paragraph 7), as stated in instant claims 1 and 9. Mydlowec et al. disclose identifying reactants and starting materials (col. 5, second and third paragraphs; col. 2, paragraphs 2 and 7; col. 3, lines 38-42 and 55-64; col. 4, third and fifth paragraphs) for the production of intermediates and target molecule (col. 4, second and third paragraphs and Figures 2, 3), as stated in instant claims 2, 7, 9, and 11. Mydlowec et al. disclose decoding each individual to produce the synthesis route and determining properties of the synthesis to produce a final product (Figures 1-4; col. 3, last three paragraphs; col. 4, third and last 2 paragraphs) including yield estimates (col. 8, paragraph 8) which represents generating a bill (list) of materials identifying quantities of all materials required in the production of the target molecule, as stated in instant claim 3. Mydlowec et al. disclose identifying solvents, reagents, and other factors including conditions required for a reaction to occur in the reaction database (col. 5, fourth through sixth paragraphs) for the production of intermediates and target molecule (col. 4, second and third paragraphs and Figures 2, 3) which represents identifying required resources and activities from the synthesis database, as stated in instant claims 4, 5, 7, 12, and 13. Mydlowec et al. disclose considering the costs of starting materials and purifying end products, as well as the time and energy requirements of reactions (col. 1, paragraph 5),

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minimizing overall costs (col. 3, lines 49-50), and querying the chemical and reaction databases for determining the yield estimate and cost estimate of the entire synthesis (col. 8, paragraphs 7 and 8) for the production of intermediates and target molecule (col. 4, second and third paragraphs and Figures 2, 3) which represents identifying costs and generating an estimated project cost, as stated in instant claims 7 and 14. Mydlowec et al. disclose accessing the molecule and reaction databases with molecule and conditions functions (col. 5, first six paragraphs) and using a program to assess the individual reaction steps and works in a forward (synthetic) direction in which a user inputs reactant molecules and reaction conditions and then resulting products are predicted (col. 6, second paragraph) which represents searching the database using chemical indicia to retrieve information regarding the synthesis project, as stated in instant claim 8. Mydlowec et al. disclose identifying required intermediate molecules (col. 4, second and third paragraphs and Figures 2, 3), as stated in instant claim 10.

Thus, Mydlowec et al. anticipate the limitations of instant claims 1-5 and 7-14.

### ***Claim Rejections – 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. (e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mydlowec et al. (US 6,571,226 B1) as applied to claims 1-5 and 7-14 above, and further in view of Kaufman (US 2001/0032029 A1).

Mydlowec et al. describe the limitations of instant claims 1-5 and 7-14, as stated in the 35 USC 102 rejection above. Mydlowec et al. describe querying the chemical and reaction databases for determining the cost estimate of the entire synthesis of a target molecule (col. 8, paragraphs 7 and 8 and col. 2, paragraph 7), as stated in instant claim 15. Mydlowec et al. do not describe generating a Gantt chart (instant claim 6), generating an offer to develop the target molecule for a customer including a price derived from the estimated total cost (instant claim 15), receiving acceptance from the customer and adding experiments to the plan to schedule required resources (instant claim 16), and tracking progress (instant claim 17).

Kauffman describes a method for operation management and determining robust processes for performing one or more tasks (abstract). Kauffman describes research and development of drug leads by pharmaceutical companies (0456). Kauffman describes using manufacturing resource planning (MRP) and scheduling to compute material volume

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requirements and timing requirements for those materials in a Gantt chart (0008, 0011) which represents generating a Gantt chart, as stated in instant claim 6. Kauffman describes using databases for resource availability and costs (0381), listing cost of every object (0117), unit cost of production (0232), a price that is paid by the resource request (customer) (0393), matching requests with offers (0041), propagating affordance values (costs) and fulfilling resource requests (0080) as well as contract terms including quantity and delivery constraints and offering a resource (0072) and communicating and confirming offers (0325, 0352), which represents generating an offer including a price and receiving acceptance from a customer, as stated in instant claims 15 and 16. Kauffman describes making sales offers for the exchange of goods including price, quantity, exchange location, exchange time, contracts, as well as purchase offers (0281) and operations management in the production of goods including supply chain management, job shop scheduling, and flow shop management (0002) and improving and modifying operations management via adding experiments (0232) which represents generating an offer and scheduling resources, as stated in instant claims 15 and 16. Kauffman describe monitoring traffic of resources, relaying resource requests and availabilities and adding transaction costs to match requested resources and offered resources (0079) which represents tracking progress, as stated in instant claim 17. Kauffman describe negotiating prices, setting delivery dates, and specifying the required quantity of materials (0005).

Mydlowec et al. state the design of synthesis routes must consider many factors, such as availability and cost of starting materials, energy and time requirements of reactions, and the cost of purifying the end products (col. 1, fourth paragraph). Kauffman states there is a need for a method to determine reliable and adaptive processes for performing one or more tasks (0017). It

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would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the method of Mydlowec et al. by using Gantt charts, generating offers of production, and tracking progress as taught by Kauffman where the motivation would have been to create a robust and reliable supply chain management, job shop scheduling, and organization structure in order to account for the effect of failures on the operation of the firm (as stated by Kauffman (0014)) since the operation management must be flexible and adaptive to changes in the firm's economic environment to improve its fitness (0015, 0226, and 0232).

Thus, Mydlowec et al., in view of Kauffman, make obvious the instant invention.

### ***Conclusion***

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (571) 272-0811.

January 16, 2007

A handwritten signature in cursive script, appearing to read 'Carolyn Smith', written in black ink.

Carolyn Smith  
Examiner  
AU 1631